UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,652	09/29/2006	Jean-Hilaire Saurat	3493-0175PUS1	2767

2292 7590 11/10/2010
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
KARPINSKI, LUKE E	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
11/10/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/587,652	SAURAT ET AL.	
	Examiner	Art Unit	
	LUKE E. KARPINSKI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-8* is/are pending in the application.

4a) Of the above claim(s) *5 and 7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/22/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendments, arguments, and remarks filed 8/25/2010 is acknowledged.

Claims

Claim 3 is canceled.

Claims 1, 2, and 4-8 are pending.

Claims 5 and 7 are withdrawn.

Claims 1, 2, 4, 6, and 8 are under consideration in this action.

Rejections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 recites the limitation "the molecular weight of the hyaluronate fragments is between 250,000 and 750,000 Da". There is insufficient antecedent basis for this

limitation in the claim. Claim 8 is dependant from claim 2, which recites a range off between 50,000 and 250,000. It is noted that there is no overlap in the range of "between 50,000 and 250,000" and "between 250,000 and 750,000" as 250,000 is not included in either range. For the purposes of compact prosecution, claim 8 will be prosecuted as dependant from claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1, 2, 4, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 6,193,956 to Liu et al. in view of USPN 4,303,676 to Balazs.

Applicant Claims

Applicant claims a composition comprising a hyaluronate fragment with a molecular weight of between 50,000 and 250,000 and between 250,000 and 750,000 Da and a retinoid selected from retinol, retinal, and esters of retinoic acid.

Applicant further claims a method of treating wrinkled skin comprising topical application of said composition.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Liu et al. teach topical compositions comprising retinol (col. 3, lines 18-32 and col. 10, lines 23-28), that retinoids are suggested for treating wrinkles and dryness of the skin (col. 1, lines 43-49), said compositions further comprising hyaluronic acid (col. 10, lines 19-28) and that hyaluronic acid provides moisturizing benefits and aids in

treating wrinkles (col. 10, lines 23-28 and col. 11, lines 11-14), as pertaining to claims 1, 2, 4, and 6.

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Liu et al. do not teach molecular weights of said hyaluronic acids as claimed in claims 1 and 2. This deficiency in Liu et al. is cured by Balazs. Balazs teaches moisturizing skin care compositions comprising more than one hyaluronate fraction, one having lower MW at 10,000 to about 200,000 Da and one having a higher MW at 1-4.5 million Da and that lower molecular weight penetrates deeper into the tissue while higher molecular weight will not penetrate as far (col. 1, lines 59-67 and col. 2, line 59 to col. 3, line 2). Balazs also teaches that said lower MW fractions are produced through heat treatment of higher (1,000,000 - 4,500,000 Da) MW fractions and gives time and temperature parameters for said mw reduction (col. 2).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Regarding the limitation of molecular weight, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Liu et al. with more than one hyaluronate fragment having different molecular weights, one between 50,000 and 750,000 and another between 250,000 and 750,000 as taught by Balazs in order to produce the invention of instant claims 1, 2, and 8.

One of ordinary skill in the art would have been motivated to do this because Liu et al. teach hyaluronic acid used in topical skin care compositions used for moisturizing purposes and Balazs teaches hyaluronic acid and hyaluronate used in moisturizing skin care compositions and molecular weight ranges to use as well as the fact that different mw ranges will penetrate to different skin layers. Therefore it would have been obvious to utilize the 1-4.5 million Da hyaluronate molecular weights of Balazs and to modify said fragments into the desired number of different MW fractions, including one between 50,000 and 250,000 and one between 250,000 and 750,000, in order to moisturize the skin at different layers, in the formulations of Liu et al. in order to produce moisturizing compositions using hyaluronate fractions with a known molecular weight ranges to penetrate to different depths in the skin.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments filed 8/25/2010 have been fully considered but they are not persuasive.

Applicant argues that Balazs teaches 2 separate MW fractions, only one of which overlaps with the claimed MW fractions.

This argument is not found persuasive because Balazs teaches how to modify a high (1-4.5 million Da) hyaluronate fraction to lower MW's for the purpose of using more than one MW fraction in order to moisturize different layers of ones skin. From the teachings of Balazs it would have been routine optimization to use the disclosed MW modification procedure to create a composition with several MW fractions to moisturize several layers of the skin with a single application of a single composition.

Applicant also argues that example 1 of Balazs teaches a low MW fraction applied to cracked skin and having no apparent effect on said cracked skin, which applicant alleges shows the criticality of a MW fraction from 1-4.5 million.

This argument is not found persuasive because Balazs states that low MW fraction penetrate more deeply into the skin and provide moisture to deep layers so one would expect that a low MW fraction would not have an apparent affect on surface cracks in the skin. The disclosure of Balazs teaches that different MW fractions penetrate to different layers and moisturize said layers, therefore it would have been obvious to create a composition having the desired MW fraction in order to moisturize the desired skin depth or to use more than one fraction in order to moisturize more than one skin layer at a time.

Conclusion

Claims 1, 2, 4, 6, and 8 are rejected.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUKE E. KARPINSKI whose telephone number is (571)270-3501. The examiner can normally be reached on Monday Friday 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEK

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616